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59. (Amended) The urethral suppository of claim 33 wherein the female urethra has a urethral length and the length of said reinforcement is greater than the urethral length.

73. (Newly Added) The urethral suppository of claim 1 wherein said reinforcement has a length in the range of about 25.0mm to about 80.0mm.

#### REMARKS

Claims 1-6, 8-64 and 73 are pending in the application. Claim 7 has been cancelled. Claim 73 is newly added.

Claims 1, 2, 7-11, 13-25, 30-34, 39-42, 44-52, and 57-64 were rejected. Claims 3-6, 12, 26-29, 35-38, 43, and 53-56 were objected to as being dependent upon a rejected base claim and were otherwise found to be allowable by the Examiner. Claims 1, 13, 16, 17, 30, 54-56, and 59 have been amended. Reconsideration is requested in view of the following remarks.

Support for the amendment to claim 1 may be found on page 18, lines 18-20 of the specification and in Figure 9. Support for the amendment to claim 13 may be found in the originally filed claim 13. Support for the amendments to claims 16, 30 and 59 may be found on page 17, line 28 through page 18, line 28 of the specification, and in Figures 2, 4 and 9. Support for the amendment to claim 17 may be found at page 15, line 25 of the specification. Support for newly added claim 73 may be found at page 18, lines 12-13 of the specification. Claims 54-56 are amended to depend on claim 53 instead of claim 52 to correct a typographical error. No new matter has been added.

#### Response to 35 U.S.C. 112 Rejection.

Claims 7, 13, 16, 17, 30, and 59 have been rejected as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner asserts that these claims are indefinite because they include a feature of a dimension relative to a patient's body part which varies depending on which patient is used.

Claims 13, 16, 17, 30, and 59 have been amended to address the rejection described above. Claim 7 has been cancelled. Applicants assert that these claims, as amended, are not indefinite.

### Response to 35 U.S.C. 102 Rejection over Giglio

Claims 1, 2, 7, 9-11, 14-21, 23, 30, 32, 33, 34, 39, 41, 42, 45-48, 50, 58-61 and 64 have been rejected as allegedly unpatentable over U.S. Patent No. 5,058,650 to Giglio (hereinafter "Giglio").

Claim 1 includes at least two features not disclosed or suggested by Giglio, namely:

"a non-meltable base member ..."; and a

"a non-meltable reinforcement ... and a meltable portion formed around ... said reinforcement" [emphasis added]

In contrast, Giglio does not disclose or suggest a non-meltable base member or a meltable portion formed around a non-meltable reinforcement.

#### Non-Meltable Base Member

With regard to claims 1, 33, 61, and 64, the Examiner asserts that Giglio discloses "a base member (26) that is capable of being non-meltable." Applicants respectfully disagree and assert that Giglio does not disclose a non-meltable base member.

The Giglio device has a conical tail 12 that includes a retention surface 26 (column 2, lines 52-54). The conical tail 12 and the retention surface 26 of the Giglio suppository must be meltable because such portions of the suppository are used to administer medication. This is required because the retention surface 26 of the conical tail 12 is employed to medicate the urethral meatus (see column 1, lines 63-66; column 2, lines 54-58; column 3, lines 29-32) and a non-meltable element would not medicate.

Accordingly, Applicants assert that the invention is patentable over claim 1 of Giglio because Giglio does not disclose or suggest a non-meltable base member.

#### Meltable Portion Formed Around Said Reinforcement

With regard to claims 1, 33, 61, and 64, the Examiner asserts that Giglio discloses "a reinforcement (16 and 22) that is capable of being non-meltable ... and a meltable portion (22) formed around a portion of said length of said reinforcement ...." Thus, the Examiner appears to suggest that the elements 16 and 22 may be interpreted as the claimed "non-meltable reinforcement" while the same element 22 may also be interpreted as the claimed "meltable portion."

Applicants respectfully disagree with the Examiner's suggested interpretation because the Giglio reference does not disclose or suggest a meltable portion formed around a non-meltable feature. In particular, Giglio does not teach or suggest a urethral suppository with an insertion surface 22 formed around the shaft 16 or around the same insertion surface 22.

First, Giglio does not disclose a single component being both non-meltable and meltable as suggested by the Examiner. As illustrated in Figures 3 and 4, the only distinctive components (as illustrated by separation lines between them) of a urethral suppository 10 of Giglio are a tail 12, a shaft 16, and a bulbous head 14. There are not any lines of distinction within any of these components to suggest a component comprises multiple distinct compositions. Therefore, the insertion surface 22 can not be interpreted as being both the claimed non-meltable reinforcement and the meltable portion formed around such reinforcement.

Further, the insertion surface 22 can not be interpreted as being formed around the shaft 16 because these two components of the Giglio urethral suppository 10 do not overlap. This is evidenced by the Giglio disclosure in column 2, lines 34-35 which states that the urethral suppository has a "bulbous head 14 secured to one end of the shaft 16." Thus, because the components are connected end-to-end, one component can not be formed around the other. Thus, the invention is patentable over claim 1 of Giglio because Giglio does not disclose or suggest a meltable portion formed around a non-meltable reinforcement.

Claim 33 includes the features of a non-meltable base member and a meltable portion formed around a non-meltable reinforcement described above with regard to claim 1 and is therefore patentable at least for the same reasons as explained above with regard to claim 1. Further, claims 2, 9-11, 14-21, 23, 30, 32, 34, 39, 41, 42, 45-48, 50, 58-61, and 64 depend from claim 1 and/or claim 33 and therefore include all the features of claim 1 and/or 33, respectively. Accordingly, Applicants assert that these claims are patentable over the cited references at least for the same reasons as discussed above with regard to the patentability of claim 1.



**Response to 35 U.S.C. 103(a) Rejection over Giglio**

Claims 24, 25, 31, 51, 52, 57, 62, and 63 have been rejected as unpatentable for allegedly being obvious in view of Giglio. These claims depend from claim 1 and/or claim 33 and therefore include all the features of claim 1 and/or 33, respectively. Accordingly, Applicants assert that these claims are patentable over the cited references at least for the same reasons as discussed above with regard to the patentability of claim 1.

**Response to 35 U.S.C. 103(a) Rejection over Giglio in view of Place**

Claims 8, 13, 22, 40, 44, and 49 were rejected as unpatentable over Giglio in view of U.S. Patent NO. 5,919,474 to Place et al. These claims depend from claim 1 and/or claim 33 and therefore include all the features of claim 1 and/or 33, respectively. Accordingly, Applicants assert that claims 8, 13, 22, 40, 44, and 49 are patentable over the cited references at least for the same reasons as discussed above with regard to the patentability of claim 1.

The claims of the application are believed to be in condition for allowance. An early action toward that end is earnestly solicited.

Respectfully submitted,

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## Appendix A

### Mark-up of claims as amended

1. (Amended) A urethral suppository for insertion into a female urethra, said suppository comprising:

- a. a non-meltable base member having a surface and sized to prevent insertion of said base member into said urethra;
- b. a non-meltable reinforcement having a length, said length having a first end and a second end, said first end attached to said base member and projecting from said base member; and
- c. a meltable portion formed around at least a portion of said length of said reinforcement, said meltable portion having a diameter which tapers from said second end toward said first end, said meltable portion sized for insertion into said urethra.

13. (Amended) The urethral suppository of claim 1 wherein said reinforcement is formed from one or more materials selected from [one or more of the groups] the group consisting of urethane, cellulose, glass, metal, rubber, and cloth.

16. (Amended) The urethral suppository of claim 1 wherein the female urethra has a urethral length and the length of said reinforcement is greater than the urethral length [of the urethra].

17. (Amended) The urethral suppository of claim 16 wherein said reinforcement has a diameter in the range of about 0.5mm to about 2.0mm [is sized for minimal or no contact with the neck of the bladder].

30. (Amended) The urethral suppository of claim 1 wherein the female urethra has a urethral length and said meltable portion has a length less than the urethral length [is sized to fit entirely within the urethra upon insertion].

54. (Amended) The urethral suppository of claim [52]53 wherein said grooves are parallel to a longitudinal axis of the meltable portion.

55. (Amended) The urethral suppository of claim [52]53 wherein said grooves are helical.

56. (Amended) The urethral suppository of claim [52]53 wherein said grooves form a passage for liquid melted from said meltable portion.

59. (Amended) The urethral suppository of claim 33 wherein the female urethra has a urethral length and the length of said reinforcement is greater than the urethral length [of said urethra].